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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0950]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The National Health and Nutrition Examination Survey (NHANES) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 11, 2018 to obtain comments from the public and affected agencies. CDC received five comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB No. 0920-0950, expires 12/31/2019) - Revision - National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States. The National Health and Nutrition Examination Surveys (NHANES) have been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics, CDC.

NHANES programs produce descriptive statistics, which measure the health and nutrition status of the general population. With physical examinations, laboratory tests, and interviews, NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States.

NHANES monitors the prevalence of chronic conditions and risk factors and are used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in the health of the U.S. population over time.

In 2019, we will implement a new data collection schedule. To increase operational efficiency, NHANES will survey a nationally representative sample over the course of a two-year cycle instead of annually. The change to a two-year cycle will permit more days allocated to each primary sampling unit (PSU). This results in less travel time, which allows more time to screen and recruit potential participants, and allows for more exam slots. As in previous years, the base sample will remain at approximately 5,000 interviewed and examined individuals annually.

NCHS collects personally identifiable information (PII). Participant level data items will include basic demographic information, name, address, social security number, Medicare number and participant health information to allow for linkages to other data sources such as the National Death Index and data from the Centers for Medicare and Medicaid Services (CMS).

A variety of agencies sponsors data collection components on NHANES. To keep burden down and respond to changing public

health research needs, NCHS cycles in and out various components. The 2019-20 NHANES physical examination includes the following components: anthropometry (all ages), 24-hour dietary recall (all ages), physician's examination (all ages, blood pressure is collected here), oral health examination (age one and older), dual X-ray absorptiometry (DXA) (ages 50+ bone density; ages 8-69 total body scan) and audiometry (ages 6-19 and 70+).

While at the examination center, additional interview questions are asked (six and older) and a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3-10 days later.

Starting in 2019, we will collect blood pressure using an automated device, instead of using manual devices. The 2019-20 survey will bring back the cognitive function test (ages 60+). We plan to add a Words-In-Noise (ages 70+) exam to the audiometry component, genetic testing related to the liver elastography exam, and a standing balance exam (ages 40+,) which includes two vision tests (contrast sensitivity and visual acuity).

NHANES also plans to conduct developmental projects during NHANES 2019-20. These may include a 24-hour blood pressure measurement pilot among NHANES participants ages 18 and older, creating and testing a social media campaign and testing

modifications to incentive amounts or how incentives are provided.

The biospecimens collected for laboratory tests include urine, blood, and vaginal and penile swabs. Serum, plasma and urine specimens are stored for future testing, including genetic research, if the participant consents. Consent to store DNA is continuing in NHANES. Collecting an oral rinse for HPV analyses is cycling back into the survey (ages 8-69 years). In addition, we will again collect a water sample in the home for fluoride.

The following analytes have been discontinued in 2018 for participants from the smoking sample subset: Aromatic Amines, Heterocyclic Amines, Urine Cotinine, Tobacco-Specific Nitrosamines, Perchlorate, Nitrates, and Thiocyanate, Urinary Arsenic, Mercury, Iodine and Metals.

Cycling out of NHANES in 2019-20 are the blood pressure methodology project, Human Papillomavirus (HPV) in serum, Aldehydes in serum, Volatile N-nitrosamines (VNAs) tobacco biomarkers, Urine heterocyclic amines, urine aromatic amines and urine tobacco-specific nitrosamines

New additions to the survey questionnaires include two questions on WIC participation, a birth to less than 24-month questionnaire module, collecting information on infant and toddler formula. We are also modifying multiple questionnaire sections so they better align with questions asked in the

National Health Interview Survey (NHIS) (OMB Control No. 0920-0214, Exp. Date 12/31/2019), compliment exam or lab content, or in order to reduce respondent burden.

Most sections of the NHANES interviews provide self-reported information to be used in combination with specific examination or laboratory content, as independent prevalence estimates, or as covariates in statistical analysis (e.g., socio-demographic characteristics). Some examples include alcohol, drug, and tobacco use, sexual behavior, prescription and aspirin use, and indicators of oral, bone, reproductive, and mental health. Several interview components support the nutrition-monitoring objective of NHANES, including questions about food security and nutrition program participation, dietary supplement use, and weight history/self-image/related behavior.

In 2019-2020, we plan to continue or expand upon existing multi-mode screening and electronic consent procedures in NHANES. Our yearly goal for interview, exam and post exam components is 5,000 participants. To achieve this goal we may need to screen up to 15,000 individuals annually.

Burden for individuals will vary based on their level of participation. For example, infants and children tend to have shorter interviews and exams than adults. This is because young people may have fewer health conditions or medications to report so their interviews take less time or because certain exams are

only conducted on individuals 18 and older, etc. In addition, adults often serve as proxy respondents for young people in their families.

Participation in NHANES is voluntary and confidential. There is no cost to respondents other than their time. We are requesting a three-year approval, with 68,417 annualized hours of burden.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)
Individuals in households	Screeners	15,000	1	5/60
Individuals in households	Household Interview	5,000	1	1.5
Individuals in households	MEC Interview & Examination	5,000	1	4
Individuals in households	Telephone Dietary Recall & Dietary Supplements	5,000	1	30/60
Individuals in households	Flexible Consumer Behavior Survey Phone Follow-Up	5,000	1	20/60
Individuals in households	Developmental Projects & Special Studies	3,500	1	3
Individuals in households	24 hour Blood Pressure Pilot	1,000	1	25

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